

REMARKS

The Applicants appreciate the Examiner's thorough examination of the subject application. Applicants request reconsideration of the subject application based on the following remarks.

Claims 1 – 5, 10, 14-17 and 27-29 are currently pending in the application. Claims 1, 4, 5, 10, 27 and 29 have been amended. Claims 3 and 28 have been canceled.

Support for the amendments to the claims can be found throughout the application as filed. No new matter has been added by the amendments to the specification or the claims.

More particularly, in the currently outstanding Official Action:

1. Claims 1-5, 10, 14-17 and 27-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The Examiner states that, "Claims 1, 2 and 27 are rejected as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. The Examiner suggests that combining the method steps of claims 1 – 3 and 27, accordingly, may obviate these rejections. Claims 1 and 27 have been amended to include the necessary steps. As such, Applicants believe the rejections have been obviated and respectfully request reconsideration.

2. Claims 1-8 are rejected under 35 USC 102(e) as being anticipated by the Kuhar reference (US Patent No. 6,531,483). In addition, Claims 1, 14 and 27 are rejected under 35 USC 102(b) as being anticipated by Blum (U.S. Patent No. 5,500,343).

Applicant respectfully disagrees and submits that the law of anticipation is well settled to the effect that:

“A claim is **anticipated** only if **each and every** element as set forth in the claim is found either expressly or inherently described in a single prior art reference” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987), MPEP 2131.
(Empahsis added)

Further, Applicant respectfully submits that this standard is not met when the Kuhar or Blum references are relied upon by the Examiner and compared with the invention claimed herein.

More particularly, Applicants respectfully submit that the Examiner has failed to construe each independent claim originally presented in this application **as a whole** in his application of the cited Kuhar or Blum references thereto. In addition, Applicant respectfully submits that the Examiner has misapprehended the teachings of the Kuhar or Blum references as they apply to the present invention in his contention that Kuhar as a 102(e) reference and Blum as a 102(b) reference teach every element of the instant method claims.

In order to fully understand the above-summarized arguments, it is necessary to fully understand what the respective references in fact do teach, disclose and/or suggest to one of ordinary skill in the art at the time the present invention was made. With regard to the teachings of Kuhar, the invention is directed to a class of binding ligands for cocaine receptors, including the use of compounds in both PET and SPECT scanning, "thus providing methods for scanning for the presence of specific cocaine receptors" (column 2, lines 21-23). In some instances, the cocaine receptors can be associated with dopamine or serotonin transporters. In contrast to Kuhar, the methods of the present invention relate to the use of ligands that bind directly to dopamine transporters and are not necessarily associated with cocaine receptors. Furthermore, the Examiner states that Kuhar teaches for the detection of Attention Deficit Disorder (ADD). Applicants wish to point out that the present invention is directed specifically to Attention Deficit Hyperactivity Disorder (ADHD). There are clear documented distinctions and differences

between ADD and ADHD. Applicants have enclosed some relevant literature for the Examiner's benefit.

With regard to the teachings of Blum, the methods of the invention relate to obtaining a DNA sample of a human and then determining the presence or absence of a particular human D₂ receptor gene allele in said sample to indicate a potential susceptibility to a compulsive disorder including ADHD. The Applicant's invention is clearly different from the Blum reference. The present invention involves administering a labeled ligand and assessing the levels of bound ligand to the dopamine transporter. The extraction of DNA and the determination of whether that DNA contains a certain allele is in no way part of the Applicant's invention.

Given the clear distinctions between the present invention and the cited Kuhar and Blum references discussed above, Applicant has searched the present specification and claims in an attempt to understand the bases of the Examiner's outstanding rejection. The result of this effort suggests that the Examiner has failed to read the claims of the present application **as a whole** as it should be in any determination of patentability. Thus, it will be understood by those skilled in the art that the present invention contains elements not found (i.e., taught, disclosed or suggested) in the Kuhar and Blum references.

3. Claims 1-5, 10,14-17 and 27-29 are rejected under 35 USC 103(a) as being unpatentable over the Kuhar reference (US Patent No. 6,531,483), in view of Elmaleh (US Patent No. 5,493,026).

The Examiner takes the position that Kuhar discloses methods of diagnostic imaging of ADD comprising administering a radiolabeled tropane compound and performing imaging thereof, while Elmaleh teaches ¹²³I-altropane is an especially effective dopamine transporter ligand which can be used for diagnostic methods using PET or SPECT. Therefore, it would be obvious to one of ordinary skill in the art to substitute ¹²³I-altropane for the dopamine transporter ligand in the method of screening for ADD.

Applicants respectfully disagree with the Examiner's basis for rejection. As mentioned above, the Kuhar reference is related to the use of cocaine receptor ligands which may or may not be associated with dopamine transporters. Furthermore, they may be used in the diagnosis of ADD, a different disorder than ADHD which is the subject disorder of the present invention. ADHD contains the element of hyperactivity, whereas ADD does not. As a consequence, the two disorders result in different symptoms and characteristics. To combine the two references of Kuhar and Elmaleh would be to achieve the aim of diagnosing ADD (not ADHD) with ^{123}I -altropane as an imaging agent, which itself has not been demonstrated by Kuhar or Elmaleh.

Furthermore, it is well-established law that the teachings of the prior art **cannot be combined** when the reference contains **no suggestion or motivation to combine them**. See ASC Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984); see also Texas Instruments v. U.S. Intern. Trade Com'n, 988 F.2d 1165, 1178, 26 USPQ.2d 1018, 1029 (Fed. Cir. 1993); Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 934-5, 15 USPQ.2d 1321, 1323 (Fed. Cir. 1990). There is no suggestion in either Kuhar or Elmaleh to combine the labeled dopamine transporter ligands and diagnostic scanning methods for diagnosing ADHD. Contrary to the Examiner's position, the primary references do not provide a "suggestion" of Applicants' claimed invention for purposes of Section 103.

These references taken alone or in combination with the other cited references simply do not teach, imply or provide any motivation for overcoming the problem of diagnosing ADHD as Applicants have done.

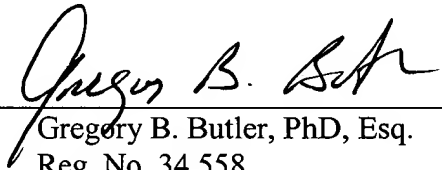
In summary, therefore, it is believed that the foregoing discussion of the Kuhar, Blum and Elmaleh references in comparison with the present invention clearly and persuasively points out the distinctions between them. It also is respectfully submitted that upon reconsideration of the present application and the cited Kuhar, Blum and Elmaleh references in view of the foregoing discussion, the Examiner will agree that the Applicant's invention is clearly and definitely patentably distinct.

For each an all of the foregoing reasons and in view of the foregoing amendment, it is believed that Claims 1-5, 10, 14-17, 27 and 29 as hereinabove amended now are in condition for allowance. Favorable reconsideration and allowance of this application, therefore, is respectfully requested in response to this communication.

Applicants believe that additional fees are not required to complete the filing requirements for the subject application or otherwise in connection with this submission. However, if a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge/credit Deposit Account No. 04-1105.

Respectfully submitted,

Date: November 24, 2003

By: 

Gregory B. Butler, PhD, Esq.
Reg. No. 34,558

EDWARDS & ANGELL, LLP
P.O. Box 9169
101 Federal Street
Boston, MA 02109
(617) 517-5595
Customer No.: 21874